

REMARKS

Claims 1, 13, and 20 are amended herein and claims 4, 6, 21, 23 and 30 were previously withdrawn. Therefore, claims 1-11, 13, 14, and 17-30 are currently pending. The amendments to the claims are fully supported by the original claims and specification. No new matter has been added. Entry of the amendments at this time is therefore respectfully requested.

Claims 1-3, 5, 7-11, 13, 14, 17-20, 22 and 24-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. U.S. Patent No. 6,566,341 for the reasons set forth on pages 2-4 of the Office Action.

As previously pointed out, the '341 patent is directed to derivatives of isoindigo, indigo and indirubin, primarily for the treatment of cancer. According to the '341 patent, the compounds of the invention prevent uncontrolled cell proliferation by regulating the cyclin-dependent kinases. Meisoindigo and NATURA specifically inhibit activities of cdk4/6, cdk2, and cdc2, thereby preventing cell proliferation and inducing cell differentiation. The '341 patent further discloses that the compounds of the invention can be useful for treating specifically Alzheimer's disease, psoriasis, cardiovascular diseases, glomerulonephritis.

The presently claimed invention is not directed to the treatment cell proliferation related diseases, such as cancer, Alzheimer's disease, psoriasis, cardiovascular diseases, glomerulonephritis, taught in the '341 patent. In contrast, the presently claimed invention is directed to the treatment of specific inflammatory-related diseases, namely arthritis, rheumatoid arthritis, an inflammatory bowel disease; multiple sclerosis; stroke; kidney failure; lupus; pancreatitis; allergy; fibrosis; anemia; a metabolic disease; a bone disease; a chemotherapy/radiation related complication; diabetes type I; diabetes type II; a liver disease; a gastrointestinal disorder; an ophthalmological disease; allergic conjunctivitis; diabetic retinopathy; Sjogren's syndrome; uveitis; a pulmonary disorder; dermatitis; HIV-related cachexia; cerebral malaria; ankylosing spondylitis; leprosy; anemia; fibromyalgia; and Parkinson disease. None of these diseases are mentioned or suggested in the '341 patent. Therefore, the '341 patent cannot be fairly said to make obvious the presently claimed invention.

The presently pending claims are based on the inventors' surprising discovery that the compounds disclosed in the '341 patent not only regulated cyclin-dependent kinases to treat cancer or cell proliferation related diseases, but also regulated cytokine expression. The inventors then further discovered that by providing lower amounts than had previously been used

to regulate cell proliferation, the same compounds could be used to regulate cytokine expression without significantly regulating cyclin-dependent kinases. For example, as disclosed in the present specification, a dosage of Meisoindigo to treat cancer (regulation of cyclin-dependent kinases) is generally about 150 mg per day, while the dosage of Meisoindigo to treat inflammatory bowel disease (regulation of pro-inflammatory cytokines) is typically only 25 mg per day. In addition, the inventors also found that if the dosage amount of the compound is sufficient to inhibit CDK, the compound typically negatively affects the inflammation healing process.

The presently pending claim 1 reflects this surprising discovery. Claim 1 requires that the amount of compound administered to the animal must be less than sufficient to substantially inhibit cyclin dependent kinases, but sufficient to treat the specific inflammatory-related disease listed by inhibiting pro-inflammatory cytokine expression or by stimulating anti-inflammatory cytokine expression.

As the '341 patent does not teach or suggest these limitations or the treatment of the specific inflammatory-related diseases recited in the claims, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-3, 5, 7-20, 22 and 24-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application no. 11/494,362 for the reasons set forth on pages 5-6 of the Office Action. Applicant will file a terminal disclaimer upon allowance of the claims if one is necessary at that time.

Claims 1-3, 5, 7-20, 22 and 24-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10-36 of copending Application No. 11/104,422 for the reasons set forth on pages 6-7 of the Office Action. Applicant will amend or cancel conflicting claims upon allowance of the claims if necessary at that time.

Claim 1 was objected to because the word "arthritis" was repeated twice in the claim. Claims 13 and 20 were objected to because the word "ulcerative" was misspelled. Claims 1, 13 and 20 have been amended. Applicant therefore respectfully requests that the Examiner withdraw these objections.

Title: "Methods of Treating an Inflammatory-Related Disease"

U.S. Serial No. 10/754,547

In view of the above, Applicant believes all claims to be in condition for allowance. If there are any questions, the Examiner is invited to call Applicant's representative Rodney Fuller at (602) 916-5404 to resolve any remaining issues to expedite the allowance of this application.

Respectfully submitted,

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Date

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